PSJ9 Exh 29

Henry Schein
135 Duryea Road
Melville, NY 11747

EXECUTIVE SUMMARY

On September 16, 2005, Kathleen Malone, Project Manager, BuzzeoPDMA visited the administrative offices of Henry Schein, Inc. to review their current Suspicious Order Monitoring procedure and process. Henry Schein is a distributor of controlled and non-controlled prescription drug products, as well as over-the-counter products. Henry Schein's customer base is predominantly office based practitioners; Henry Schein also distributes to a lesser degree to hospital, clinic, government and wholesaler accounts.

In year 2002, J. Schein, R.Ph., conducted a study averaging all orders for each product placed over one year's time to determine the significant threshold for each product, cumulative, for six months. The current system is based upon this data; modifications have been made, new products added since the 2002 study. Entry of the threshold is a manual process conducted by the Verification Team. The Verification Team is a dedicated team that monitors on a daily basis, those orders that the system flags as suspicous and places on a "pend" status. The team is also responsible for customer registration verification.

The purpose of this review was to determine if the system is operating in accordance with DEA regulations and whether the thresholds are in line with best industry practice.

Immediately following are the findings that were noted during the review. Each finding, where appropriate, indicates the regulatory requirement to which it relates.

Henry Schein Inc.
Controlled Substance Monitoring and Reporting Process

21CFR 1304.74 (b) states "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency".

Standard Operating Procedure Document R-03.07 specifies H Schein uses a computerized monitoring system to highlight suspicious controlled substance orders to identify orders of unusual size, frequency and deviation from normal patterns. Thresholds have been set and are reviewed by HSI's staff pharmacist.

FINDINGS

1. Finding

The HSI system is based solely upon excessive order thresholds. Orders are not highlighted for frequency or deviations from patterns. When an order "pends", the investigation conducted by the Verficiation Team includes the review of ordering frequency and patterns, however, this review will only occur if the order reaches the threshold limit.

Recommendation

It is recommended a review of the program be conducted to ascertain whether orders can be highlighted for not only unusual size, but also for ordering frequency.

2. Finding

There is no formal process in place to review threshold data on a periodic basis, nor is there currently a staff pharmacist available to review the system thresholds as stated in the standard operating procedure. The data from the year 2002 study was not available for review.

Recommendation

It is recommended thresholds be reviewed on a periodic basis to ensure they remain current and applicable. During this review we discussed the conduct of a statisitical analysis of selected products from the HSI product list to determine excessive thresholds. BuzzeoPDMA will research this analysis and contact HSI to collect the appropriate data points.

3. Finding

It was stated approximately 97% of HSI's customer base are office based accounts made up of medical doctors, dentists, mid-level practitioners and veterinary practitioners. The HSI inventory of available controlled and List I containing drug products is extensive. Currently there is no formal process in place to assess the appropriateness of the customer's medical practice in relation to the drug product being ordered. Attempts are made when new products are added to the inventory, to search the intranet for product indications to assess the use of the product in relation to the practitioner cateogry. For example, methylphenidate products are blocked from being ordered by the dental customer base; but CIII regulated steroids and CII Actiq lozenges may be ordered by any category of practitioner.

internet?

Recommendation

It is recommended a formal review be conducted of controlled drug and List I containing products to ascertain whether there are products that may not be appropriate for all categories of practitioners to order and receive. As new products are added to the HSI inventory, this review should be conducted prior to launching the product for sale.

4. Finding

Orders that are highlighted as suspicious are all investigated; those that are cleared from suspicious status are released; those that are not, are cancelled. At the end of each month, two reports are run and submitted to the appropriate Field Offices of the DEA. The first report includes those pended orders that were cleared from suspicious status, the second report reflects those orders that were deemed suspicious and cancelled.

Requirement

21CFR 1304.74 (b) states "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency".

immediately upon discovery

Recommendation

While HSI has been using their current reporting process for several years, it is recommended consideration be given to filing the suspicious order report for those orders not released from suspicious status, to the DEA immediately. If HSI continues to find value in submitting orders released from suspicious status to the local offices of DEA, these reports could continue to be submitted at month end. This report however, is not required by the Administration. It should be kept in mind submittal of this data will not relieve HSI from liability should a registrant on this report be investigated by the Administration for excessive or suspicous ordering.

5. Finding

When an order pends as suspiscious, the order and the customer patterns are reviewed. If it still remains suspicious, a letter is sent to the customer requiring an explanation of the order. A pending order will not be released without a return letter from the customer. When the letter is received and reviewed, if the explanation is found reasonable, the order is released and the letter retained on file. A notation is made in the system that this letter has been received. This letter then is used to clear additional excessive orders for the same customer.

Same cust letter

Recommendation

It is recommended a careful review of the existing letter be conducted, each time the same customer exceeds the threshold; even if the same product or product type is ordered in what the system captures as an excessive quantity. If this letter will be relied upon to clear each future excessive order by the customer a careful review should be made to ensure the explanation remains viable.

6. Finding

Pseudoephrine containing product orders are captured in the suspicious order monitoring system. Orders for physician personal use were noted. One letter from a physician indicated their order for some 51 bottles of 100's was to supply the family, all having seasonal allergies, for one year, as well as to avoid HSI shipping charges for a larger order.

Recommendation

Orders of this nature should be very carefully reviewed. The appropriateness of an increase in the size of an order of a sensitive product, just to avoid shipping charges should be carefully considered.

It cannot be stated too strongly that DEA and many of the states are combating a major methamphetamine clandestine laboratory problem. Both DEA and the affected states consider diverted pseudoephedrine as a major contributor to this problem. DEA is under considerable pressure from Congress to curb methamphetamine production. Therefore, for the last several years DEA has cracked down hard on handlers of pseudoephedrine drug products and aggressively pursued firms for even inadvertent violations. DEA fully expect stringent suspicious order monitoring systems be in place for pseudo containing products.

set up at

7. Finding

A pend order was noted for a dentist, that was actually an account coded as a medical customer. It was stated this occurs so that one division can "book" the orders. Therefore,

a product that may be blocked or found inappropriatea for one category of practitioner, could in fact be supplied to them.

Recommendation

It is recommended this practice be reviewed and only those products that are appropriate for a category of practictioner be allowed for shipment.

REVIEW

The intent of this review was to provide Henry Schein with feedback on their suspicous order monitoring system and to ascertain whether their system and thresholds are in line with current industry practice.

Henry Schein, Inc. fulfills the DEA requirement of designing and operating a system that will detect suspicious orders. Thresholds have been set for each product. They review each order deemed suspicous, prior to release or cancellation. They solicit customer feedback when an order is deemed suspicious. If feedback is not received the order is cancelled. Suspicious orders are reported to the Administration, however, they are not reported upon discovery. Orders released from suspicious status are also reported, which is not a requirement.

Generally, wholesale distributor practices reveal two suspicious order systems. One where thresholds are set for each individual account, the other by customer category, i.e. practicioner, wholesaler, hospital / clinic.

Customer or category orders which exceed thresholds, or exceed a set number of orders per month, are placed on hold or captured on a suspicious order report which is sent to the Administration at each months' end. The latter would not be considered a robust monitoring system, as all suspicious orders are shipped and reported to DEA without an investigation. A system that holds or pends orders flagged by the system with a subsequent investigation of each is the preferred and DEA expected system, and is the procedure Henry Schein follows.

With regard to setting thresholds it is difficult to look at a list of products with quantities applied to each and determine if they seem reasonable. Without assessing an accounts' ordering history, or assessing the ordering history of a customer category, it would be difficult to ascertain whether that specific threshold is excessive for that account / category. The current system pends every wholesaler order, as sales to this category of customer will almost always exceed that of practitioners. This process does not seem efficient.

BuzzeoPDMA is researching with our statisticians, what data points would be required to review for a statistically significant list of thresholds.

Qualifications:

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the DEA regulations and our experience with them. Many of the requirements of the DEA and regulations there under are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that DEA would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of DEA regulations, if any that may be noted in this report.